

CHS  
JUN 28 2006  
PATENT & TRADEMARK OFFICE  
**S/N 10/009,036**

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Sanberg et al.

Examiner: Kimberly A. Ballard

Serial No.: 10/009,036

Group Art Unit: 1649

Filed: 9/30/2002

Docket: LAY-014PCTUS

Title: Cell Therapy for Chronic Stroke

**Declaration Under 37 CFR §1.131**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

We, Paul R. Sanberg, Douglas Kondziolka, Michael McGrogan and Gary L. Snable, hereby declare that;

1. We, Paul R. Sanberg, Douglas Kondziolka, Michael McGrogan and Gary L. Snable, are co-inventors of the above-captioned patent application.

2. The invention was made on or before July 1, 1998, the date on which the first implantation of cells in humans was performed. This event is substantiated in a press release on July 1, 1998, provided with the Information Disclosure Statement. Even before human implantation, a protocol must be developed and submitted to the FDA in the form of an Investigational New Drug application. Also prior to implantation in humans, the protocol must be approved by an Institutional Review Board, both for patient safety. All these activities took place over a period of months prior to the first patient implantation of cells for stroke treatment. The invention was at no time abandoned. Therefore, we propose an invention date that is a year prior to the April 27, 1999, filing date of the first provisional application No. 60/131,230.

3. Earlier work with stroke models (e.g., in rats) was used as the basis to propose that similar treatment should be tried in humans. Such an event had been predicted based on success in rat stroke models; however, many pharmaceutical and other treatments in stroke animal models have not translated into successful therapeutics in humans. Nevertheless, this stroke model is the only widely accepted model.

4. Our invention was not in public use or on sale in this country or another, or patented or described in a printed publication in this or any foreign country, for more than a year prior to our filing of the parent provisional application 60/131,230, on April 27, 1999.

*We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.*

Respectfully submitted,

5-24-06

Date



Paul Sanberg

Date

Douglas Kondziolka

Date

Michael McGrogan

Date

Gary Snable

JUN 28 2006

PATENT &amp; TRADEMARK OFFICE

APR 14

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**DECLARATION FOR UTILITY OR  
DESIGN  
PATENT APPLICATION  
(37 CFR 1.63)**

Declaration Submitted With Initial Filing

OR

Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	LAY-014PCTUS
First Named Inventor	Sanberg
<b>COMPLETE IF KNOWN</b>	
Application Number	10/009,036
Filing Date	September 30, 2002
Art Unit	1649
Examiner Name	Ballard

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Cell Therapy for Chronic Stroke

*(Title of the Invention)*

the specification of which

is attached hereto

**OR**

was filed on (MM/DD/YYYY) 9/30/02 as United States Application Number or PCT International

Application Number 10/009,036 and was amended on (MM/DD/YYYY)   (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	Certified Copy Attached? NO
60/131,230	United States of America	04/27/1999	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
60/144,785	United States of America	07/20/1999	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PCT/US00/06912	PCT	03/16/2000	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

[Page 1 of 2]

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**DECLARATION — Utility or Design Patent Application**

Direct all correspondence to:  The address associated with Customer Number: 51951 OR  Correspondence address below

Name

Address

City

State

ZIP

Country

Telephone

480-275-8302

Email

bjluther@cox.net

**WARNING:**

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<b>NAME OF SOLE OR FIRST INVENTOR:</b>	<input type="checkbox"/> A petition has been filed for this unsigned inventor
--	---

Given Name (first and middle [if any])	Family Name or Surname
--	------------------------

Paul R.	Sanberg
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Inventor's Signature	Date
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Residence: City Spring Hill	State Florida	Country USA	Citizenship USA
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Mailing Address

11751 Pilot Country Drive

City Spring Hill	State Florida	Zip 34610	Country USA
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Additional inventors or a legal representative are being named on the \_\_\_\_\_ supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

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**DECLARATION****ADDITIONAL INVENTOR(S)****Supplemental Sheet**Page 2 of 2

<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Douglas		Kondziolka	
Inventor's Signature			Date
Pittsburgh Residence: City	Pennsylvania State	US Country	Canadian Citizenship
1005 West Waldheim Road Mailing Address			
Pittsburgh City	PA State	115215 Zip	USA Country
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Michael		McGrogan	
Inventor's Signature			Date
San Carlos Residence: City	California State	USA Country	US Citizenship
1405 Cedar Street Mailing Address			
San Carlos City	CA State	94070 Zip	USA Country
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Gary	L.	Snable	
Inventor's Signature	<i>Mary R. Snable</i>		Date <u>03/11/2006</u>
San Francisco Residence: City	California State	USA Country	US Citizenship
1201 California Street Mailing Address <u>Apt. 102</u>			
San Francisco City	CA State	94109 Zip	USA Country

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S/N 10/009,036

PATENT

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Examiner: Kimberly A. Ballard

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Respectfully submitted,

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Date

May 25, 2006

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Date

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Paul Sanberg



Paul Sanberg

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Date

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Michael McGrogan

---

Date

---

Gary Snable



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PTO/SB/01 (10-05)

Approved for use through 07/31/2006. OMB 0651-0032  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

## DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

Declaration Submitted With Initial Filing

OR

Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	LAY-014PCTUS
First Named Inventor	Sanberg
<b>COMPLETE IF KNOWN</b>	
Application Number	10/009,036
Filing Date	September 30, 2002
Art Unit	1649
Examiner Name	Ballard

### I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

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(Title of the Invention)

the specification of which

is attached hereto

OR

was filed on (MM/DD/YYYY) 9/30/02 as United States Application Number or PCT International

Application Number 10/009,036 and was amended on (MM/DD/YYYY)   (if applicable).

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**DECLARATION — Utility or Design Patent Application**

Direct all correspondence to:  The address associated with Customer Number: 51951 OR  Correspondence address below

Name

Address

City

State

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Country

Telephone

480-275-8302

Email

bjluther@cox.net

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NAME OF SOLE OR FIRST INVENTOR:

 A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])

Paul R.

Family Name or Surname

Sanberg

Inventor's Signature

Date

Residence: City

Spring Hill

State

Florida

Country

USA

Citizenship

USA

Mailing Address

11751 Pilot Country Drive

City

Spring Hill

State

Florida

Zip

34610

Country

USA



Additional inventors or a legal representative are being named on the

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**DECLARATION****ADDITIONAL INVENTOR(S)  
Supplemental Sheet**Page 2 of 2

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Given Name (first and middle (if any))		Family Name or Surname	
Douglas		Kondziolka	
Inventor's Signature			Date <i>Mar 10/2006</i>
Pittsburgh Residence: City	Pennsylvania State	US Country	US Citizenship
1005 West Waldheim Road Mailing Address			
Pittsburgh City	PA State	15215 Zip	USA Country
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1405 Cedar Street Mailing Address			
San Carlos City	CA State	94070 Zip	USA Country
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(Title of the Invention)

the specification of which

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Given Name (first and middle [if any])	Family Name or Surname
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Paul R.	Sanberg
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Inventor's Signature	Date
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Residence: City Spring Hill	State Florida	Country USA	Citizenship USA
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11751 Pilot Country Drive

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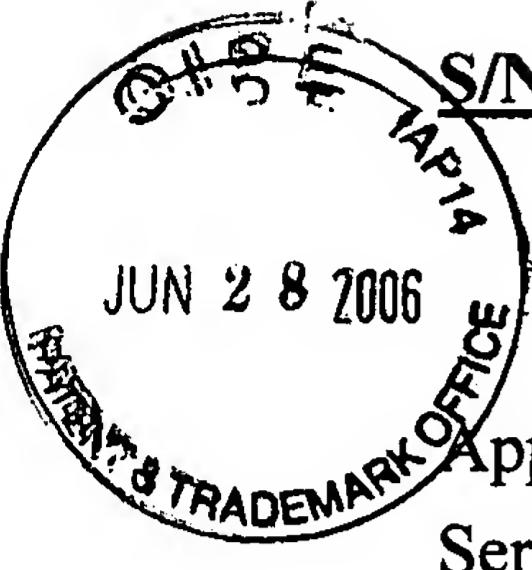
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Given Name (first and middle (if any))		Family Name or Surname	
Michael		McGrogan	
Inventor's Signature			Date <u>3/13/06</u>
San Carlos Residence: City	California State	USA Country	US Citizenship
1405 Cedar Street Mailing Address			
San Carlos City	CA State	94070 Zip	USA Country
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Gary		Snable	
Inventor's Signature			Date
San Francisco Residence: City	California State	USA Country	US Citizenship
1201 California Street Mailing Address			
San Francisco City	CA State	94109 Zip	USA Country

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S/N 10/009,036

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Sanberg et al.  
Serial No.: 10/009,036  
Filed: 9/30/2002  
Title: Cell Therapy for Chronic Stroke

Examiner: Kimberly A. Ballard  
Group Art Unit: 1649  
Docket: LAY-014PCTUS

**Declaration Under 37 CFR §1.131**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

We, Paul R. Sanberg, Douglas Kondziolka, Michael McGrogan and Gary L. Snable, hereby declare that;

1. We, Paul R. Sanberg, Douglas Kondziolka, Michael McGrogan and Gary L. Snable, are co-inventors of the above-captioned patent application.
2. The invention was made on or before July 1, 1998, the date on which the first implantation of cells in humans was performed. This event is substantiated in a press release on July 1, 1998, provided with the Information Disclosure Statement. Even before human implantation, a protocol must be developed and submitted to the FDA in the form of an Investigational New Drug application. Also prior to implantation in humans, the protocol must be approved by an Institutional Review Board, both for patient safety. All these activities took place over a period of months prior to the first patient implantation of cells for stroke treatment. The invention was at no time abandoned. Therefore, we propose an invention date that is a year prior to the April 27, 1999, filing date of the first provisional application No. 60/131,230.
3. Earlier work with stroke models (e.g., in rats) was used as the basis to propose that similar treatment should be tried in humans. Such an event had been predicted based on success in rat stroke models; however, many pharmaceutical and other treatments in stroke animal models have not translated into successful therapeutics in humans. Nevertheless, this stroke model is the only widely accepted model.

4. Our invention was not in public use or on sale in this country or another, or patented or described in a printed publication in this or any foreign country, for more than a year prior to our filing of the parent provisional application 60/131,230, on April 27, 1999.

*We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.*

Respectfully submitted,

---

Date

Paul Sanberg

---

Date

Douglas Kondziolka

---

Date

Michael McGrogan

May 24, 2006  
Date

Gary Snable  
Gary Snable



S/N 10/009,036

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Sanberg et al.

Examiner: Kimberly A. Ballard

Serial No.: 10/009,036

Group Art Unit: 1649

Filed: 9/30/2002

Docket: LAY-014PCTUS

Title: Cell Therapy for Chronic Stroke

**Declaration Under 37 CFR §1.131**

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Alexandria, VA 22313-1450

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Respectfully submitted,

---

Date

Paul Sanberg

---

Date

Douglas Kondziolka

5/25/06  
Date

Michael McGrogan  
Michael McGrogan

---

Date

Gary Snable

Aug. 31 2005 01:44PM P2  
JUN 28 2006Aug. 31 2005 01:44PM P2  
JUN 28 2006**BEST AVAILABLE COPY**

PTO/SB/01 (10-05)

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**DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)** Declaration Submitted With Initial Filing

OR

 Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	LAY-014PCTUS
First Named Inventor	Sanberg
<b>COMPLETE IF KNOWN</b>	
Application Number	10/009,038
Filing Date	September 30, 2002
Art Unit	1849
Examiner Name	Ballard

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Cell Therapy for Chronic Stroke

(Title of the Invention)

the specification of which

 Is attached hereto

OR

 was filed on (MM/DD/YYYY) 09/30/02 as United States Application Number or PCT International

Application Number 10/009,038 and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.59, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(e)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(e) of any PCT International application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	Certified Copy Attached? NO
60/131,230	United States of America	04/27/1998	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
60/144,726	United States of America	07/23/1999	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PCT/US00/06912	PCT	03/16/2000	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

 Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

[Page 1 of 2]

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PTO/SB/04 (10-05)

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**DECLARATION — Utility or Design Patent Application**

Direct all correspondence to:  The address associated with Customer Number: 51851 OR  Correspondence address below

Name

Address

City

State

ZIP

Country

Telephone

480-275-8302

Email

bjluther@cox.net

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Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any]) Paul R.		Family Name or Surname Sanberg	
Inventor's Signature 			Date 6-27-06
Residence: City Spring Hill	State Florida	Country USA	Citizenship USA
Mailing Address 11751 Pilot Country Drive			
City Spring Hill	State Florida	Zip 34610	Country USA
<input checked="" type="checkbox"/> Additional inventors or a legal representative are being named on the _____ supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.			

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**DECLARATION****ADDITIONAL INVENTOR(S)  
Supplemental Sheet**Page 2 of 2

<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Douglas		Kondziolka	
Inventor's Signature		Date	
Pittsburgh Residence: City	Pennsylvania State	US Country	US Citizenship
1005 West Waldheim Road Mailing Address			
Pittsburgh City	PA State	15215 Zip	USA Country
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Michael		McGrogan	
Inventor's Signature		Date	
San Carlos Residence: City	California State	USA Country	US Citizenship
1405 Cedar Street Mailing Address			
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<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
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